

Natural and Non-prescription Health Products Directorate (NNHPD) Updates

Performance Standards for NHP Applications
March 24, 2023

YOUR HEALTH AND SAFETY... OUR PRIORITY.



Outline:

- NHP workload update:
 - Performance
 - Product
 - Site
 - Supporting the application process
- Recent systems update





NHP Workload update: Product and Site licence applications

Non-COVID Submissions Summary (April 1, 2022 to February 28, 2023)

Product Licence Submissions:

- Licensed 6,975 NHPs
56% Class I; 13% Class II; 31% Class III
- Refused 1,669 submissions

Site Licence Submissions:

- Licensed or renewed 847 site licences
- Refused 375 submissions

Client Service Inquiries:

- Received **6,931** inquiries
 - 98% of inquiries received a response



Non-COVID Product Licence Applications (April 1, 2022 to February 28, 2023)

- **Class I:** 98.2% year-to-date performance for new applications and amendments against the 60-day service standard
 - Total Refusal Rate: **17%**
- **Class II:** 95.1% year-to-date performance for new applications and amendments against the 90-day service standard
 - Total Refusal Rate: **35%**
- **Class III:** 56.1% year-to-date performance for new applications and amendments against the 210 day service standard
 - Total Refusal Rate: **17%**
 - Unable to meet 90% until sustainable funding is obtained



90% Performance
target for 2022-23

To maintain fairness, all applications are treated consistently based on the date received - applications will not be expedited/prioritized

Product Licence Submissions (Non-COVID):



Overall Refusal Rate: 19%

Class III IRN Rate: 90%

Common deficiencies:

- Screening deficiencies: Claims, risk information, finish product specifications and no evidence; Brand names (Class I)
- Assessment deficiencies:
 - For Class III applications we are still seeing a lot of refusals on minimum criteria; such as, links and abstracts being provided instead of full-text evidence.
 - Failure to respond to all points on an IRN, comply with options provided or failure to correctly respond to the IRN

REMINDERS:

- For Class II and III applications the web form **does not validate against monographs**. Applicants should ensure that pre-cleared information claims and risk information are supported by dosing information.
- Unsolicited changes are not accepted as per section 6.2.2 of the NHP MAP resulting in refusal

Notifications

- Processed 82% of the notifications received in 2022
 - company updates prioritized
- **Market Notifications:**
 - Currently an additional 186 market notification webforms have been updated in the LNHPD. We have approximately 209 remaining

Monograph Updates

- [NHP MAP: Section 7.2 - Monograph Updates](#)

Working Together

- Auto-reply: Increasing transparency
 - Regular updates to the auto-reply
- Client Services response timeframes
 - Direct replies: 1-2 days
 - Subject matter experts: 6-7 days



Site Licence Applications (April 1, 2022 to February 28, 2023)

- **Stream I:** 49% year to date performance for new applications and amendments
 - Total Refusal Rate: 28%
 - Performance target for 2022-2023: unable to meet 90% until sustainable funding is obtained
- **Stream II:** 43% year to date performance for new applications and amendments
 - Total Refusal Rate: 42%
 - Performance target for 2022-2023: unable to meet 90% until sustainable funding is obtained
- **Renewals:** completed 535 renewal submissions this fiscal year
 - Total Refusal Rate: 13%
 - Performance target for 2022-2023: clear the backlog of renewals, interim measures for FSRNs remain in effect until further notice
 - Applicants that fail to submit an application to renew at least 30 days before their site licence expires will NOT be prioritized
- **COVID SL transition completed (February 2023):** 73 licensed and 208 refused/withdrawn



To maintain fairness, all applications are treated consistently based on the date received - applications will not be expedited/prioritized

Site Licence Submissions (Non-COVID):

Overall Refusal Rate: 27%

Overall IRN Rate: 61%



Common Deficiencies:

1. Failure to submit an application to renew the site licence at least 30 days before the licence expiry
2. Failure to submit all aspects of the application in a way that supports an efficient review (e.g., Documents are not in one of the two official languages (EN or FR); documents not organized or easily distinguishable)
3. Companies provide records (e.g., stability and finished product testing) for products that are not intended for the Canadian market

REMINDER:

- Applications must be submitted electronically via ePost Connect using the Web SLA v3.0 form. Paper based or PDF versions are no longer accepted and will be refused.



Improvements to support site licensing and quality overview

- ✓ **Internal template updates** support consistency between reviews- Fall 2023
- ✓ **Increased efficiencies in Site Licensing** - Summer/Fall 2022
 - Continue risk-based administrative renewals
 - Looking to provide advance notice to lighten burden of application; and working with ROEB on leveraging inspection ratings
- ✓ **Targeted updates to FPS User Guide***- December 15, 2022 - (see Annex)
 - Test parameters added; changes to tolerance limits; changes to parameters applied to specific ingredients in alignment to the Quality of Natural Health products Guide
- ✓ **Site Licencing Bulletins** – #3 and #4 effective March 21, 2023- (see Annex)
- ❑ **Risk-based criteria for quality amendments** - Spring 2023
 - Quantity tolerance limits exceeding Prescription Drug List, Cosmetic Ingredient Hotlist, or missing an upper or lower limit
- ❑ **Guidance updates** (Quality guide, GMP Guidance Document)- Consult Fall 2023



Tips to support with ALL site licence application:

- ✓ Submit an application through the correct channel (*see Annex*)
- ✓ Read Site licence Bulletins- bulletin #3 (format/structure) and #4 (refusal criteria) are implemented as of **March 21st** (*see Annex*)
- ✓ Provide evidence for products that are intended for the Canadian Market
- ✓ Respond to an information request notice (IRN) on time (e.g., multiple requests for extensions)
- ✓ Monitor your email, including junk mail, for a notification from the ePost Connect System, to not miss IRNs or the licensing decisions
- ✓ Submit a complete and compliant application
 - ✓ e.g. follow the WebSLA checklist, no missing records, legible documents, english or french documents



Tips to support with site licence renewals:

- ✓ Submit an application to renew the site licence at least 30 days before the licence expiry
- ✓ Submit ONLY an application to renew a site licence (i.e., requests for modification like to add a new foreign site must be submitted as amendments)
- ✓ Submit complete Summary of Net Changes (SNC) form
 - ✓ records 1-8 (storage, pest control, training, sanitation, finished product testing, QA release, recall, stability) within 12 months
 - ✓ Form is dated and signed
- ✓ If renewal missed, a company that has previously conducted activities should submit SNC rather than QAR
- ✓ Per Bulletin #4, there is a one-time exemption to not provide evidence if no activities have been conducted for 12 months
 - ✓ A site licence is only needed for those conducting activities, so if not conducting activities beyond this, it is recommended to relinquish site licence and reapply in future when activities are intended.

Update on Inspections

- NNHPD is actively supporting colleagues in ROEB for inspection work.
 - Focus is on re-inspections of those considered non-compliant during the pilot as well as new inspections
 - Similar criteria to those used during the pilot, with some exceptions re COVID restrictions no longer being in effect and scope (no longer limited to importers and manufacturers)
- ROEB has started inspection planning for the 23/24 FY
- NNHPD is exploring leveraging inspection ratings during site licence review
- The **NHP GMP Inspection pilot** results are available at:
<https://www.canada.ca/en/health-canada/services/inspecting-monitoring-drug-health-products/drug-health-product-inspections/natural-health-products-good-manufacturing-practices.html>

Upcoming System Updates

New Look and Feel- Natural Health Products Database

MENU ▾

[Canada.ca](#) > [Health Canada](#) > [Drugs & Health Products](#) > [Natural Health Products](#) > [Natural Health Products Ingredients Database](#)

Natural health products ingredients database

The Natural health products ingredients database (NHPID) provides an electronic tool which enables members of the public to access information on the following topics:

- acceptable medicinal and non-medicinal ingredients used in Natural health products (NHP)
- standard terminology used by the Natural health products online system (NHP Online System), known as "Controlled vocabulary", referring to acceptable quality test methods, dosage forms, non-medicinal ingredient purposes, and so on.
- pre-cleared information such as single ingredient monographs, product monographs and abbreviated labelling standards (AbLS)

Members of the public can search these topics using the following search functions:

Ingredient search

In the Search for ingredient field, enter any part of an ingredient name or Chemical abstract service (CAS) number. Select an ingredient role from the Role dropdown list, and click on the Search button to display the search results for the query.

Please note that the homeopathic ingredient names and sources are mainly in English because it represents information coming from one French language pharmacopoeia and four English language pharmacopoeias. Fully bilingual ingredients will be available in the near future.

Search for ingredient:

Role:

[Search Ingredients](#)

Controlled vocabulary search



Date database last changed:
2023-03-09 02:37:09

[What's new in the NHPID](#)

Organism - Echinacea angustifolia

NHPID name: Echinacea angustifolia

Reference: [UNAVA](#)

Proper name(s): [Echinacea angustifolia](#)

Common name(s):

- [Black sampson](#)
- [Black-sampson echinacea](#)
- [Echinacea](#)
- [Kansas snakeroot](#)
- [No English equivalent to synonym "Echinacée angustifolia"](#)
- [Narrow-leaf coneflower](#)
- [Narrow-leaf echinacea](#)
- [Narrow-leaf purple-coneflower](#)

Category: Approved Herbal Name

Monograph(s): [Echinacea Angustifolia](#)

Internal AbLS: [Echinacea angustifolia \(AC\)](#)

Schedule 1: [Plant and plant material](#)

Source material(s): [Echinacea angustifolia \(Parts: Whole plant\)](#)

Preparations: [Dry, Fresh](#)

Roles

Medicinal

Rationale: Classified as an NHP under Schedule 1 Item 1 (plant or plant material) of the NHP Regulations.

Reference: [NNHPD](#)

Date modified: 2023-01-30

- Improve the stability of the NHPID
- Become compliant with the Governments of Canada Web Content Accessibility Guidelines (WCAG)
- Same functionality as before
- Launching Summer 2023

Automated Site License Publication Search

Site Licence Holders List

From [Health Canada](#)

The site licence holder list indicates sites that have been authorized to manufacture, package, label and/or import natural health products by Health Canada.

Foreign site reference numbers are issued to sites outside of Canada which have been assessed against Part 3 of the Natural Health Products Regulations (NHPR) for Good Manufacturing Practices (GMPs) and issued a reference number. Please note that a reference number is for reference only and that these sites have not been licensed by Health Canada.

Search

Company Name

Category

Site Licence

FSRN: Foreign site reference number

License Status

Active

Licence Number

Search

Reset

- Improved search function
- Up-to-date information
- Launching summer 2023

Search results

From [Health Canada](#)

[New search](#)

Filter items

Showing 1 to 10 of 803 entries | Show **10** entries

Search results

Company Name	Address (Street#, Suite)	City	Province/State	Country	Postal Code	Licence Number	License Status
102089353 Saskatchewan Ltd/NutraTech Solutions Inc.	10-721 66th Street	Saskatoon	Saskatchewan	Canada	S7P 0E4	302554	Active
1045158 B.C. Ltd. dba PURA	11871 Hammersmith Way	Richmond	British Columbia	Canada	V7A 5E5	301910	Active

Q&A



Natural and Non-Prescription Health
Products Directorate (NNHPD)

Contact us directly at:

nnhpd.consultation-dpsnso@hc-sc.gc.ca

Reminder: Product Tips and Tricks

- Ensure submission package is of high quality and that the evidence provided supports safety and efficacy of the product according to the recommended conditions of use (e.g. method of preparation, daily dose, claim, etc.) prior to submission.
- When using PCI (monographs to support the conditions of use of the product) ensure that the boxes indicating meeting PCI are checked (safety; efficacy; and/or quality). This will help direct the reviewers to the appropriate information and save valuable time and effort.

Class III backlog

There are approximately 2038 files in Class III (this includes files that are in queue and working), of those approximately 520 files are past the 210 day service standard.

- Screening files at 134-165 days;
- Assessing files at approx. 224 days;
- Issuing decisions at approx. 282 days*

**taken from files licensed in the last two months that required an IRN, note there is a lot of variation*

Reminder: Site licensing Bulletins

Bulletins available at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/applications-submissions/site-licensing/bulletin.html>

- **#1- Foreign site reference number (FSRN) interim measures -April 2022**
 - Note: These measures remain in effect until further notice
- **#2 Version 3.0 of Web SLA -April 2022**
- **#3 SL Submission Format and Structure– in effect March 21, 2023**
- **#4 SL Submission Refusal Criteria – in effect March 21, 2023**

Reminder: FPS User Guide

FPS User Guide available at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/finished-product-specifications-form-user-guide.html>



Reminder: How to apply for site licence

1. Enroll as an ePost trading partner (See link)

2. Submit through ePost Connect™

- application packages through ePost Connect™ ‘New NHP applications’ conversation
 - conversation initiated by nhpsn.ePostel.applications@hc-sc.gc.ca
 - *All post-licence amendment, notification or renewal requests must be sent via ePost Connect™ through a new message*
- correspondence regarding Information Request Notices and Clarimails through submission-specific ePost Connect™ conversations
 - conversations initiated by nhpsn.ePostel.correspond@hc-sc.gc.ca
 - *New applications and other requests are **not accepted** through these conversations.*

3. Delegated users or third party individuals

- must have a designated party authorization form from the product or site licence holder to submit a new application.

Additional details available at: [Guidance document on how to interact with the Natural and Non-Prescription Health Products Directorate electronically](#)